



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/645,706	08/24/2000	Keith V. Wood	341.005US1	3329

21186 7590 04/29/2004

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.  
P.O. BOX 2938  
MINNEAPOLIS, MN 55402

EXAMINER

PROUTY, REBECCA E

ART UNIT PAPER NUMBER

1652

DATE MAILED: 04/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/645,706

Applicant(s)

WOOD ET AL.

Examiner

Rebecca E. Prouty

Art Unit

1652

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 09 April 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:


Claim(s) allowed: none.

Claim(s) objected to: none.

Claim(s) rejected: 1-9, 11, 12, 14, 15, 18, 20, 21, 24-39, 41-45, 47, 60-63, 67 and 68.

Claim(s) withdrawn from consideration: 64.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

  
Rebecca E. Prouty  
Primary Examiner  
Art Unit: 1652

Continuation of 2. NOTE: the new claims, particularly Claims 69 and 70 present new limitations which would require further search and consideration..

The rejection under 35 U.S.C. 112, second paragraph as being indefinite in the recitation of "transcription regulatory sequences composition", "a reduced number of transcription factor binding sequences" and/or "a reduced number of intron splice sites, poly(A) addition sites and promoter sequences" is maintained. Applicants argue that the terms "transcription factor binding sequences", "intron splice sites", "poly(A) addition sites" and "promoter sequences" are conventional in the art. This is acknowledged. However, in the art these terms define a group of sequences related by function. The art does not define clearly **what** sequences are included in the group. Since applicants invention requires a skilled artisan to **quantify** the number of such sequences it is imperative that the artisan know explicitly what sequences are to be included and what sequences are not so one can in fact count them. While the art clearly defines **some** specific sequences which fall into each group (for example AAUAAA as a polyadenylation sequence) many other sequences may have the same function and not all such sequences are known and taught by the art.

The rejections of the claims under 35 U.S.C. 112, first paragraph for lack of written description and lack of enablement are maintained. Applicants argue that the specification provides

Art Unit: 1652

representative species of luciferases that have modifications relative to the wild type sequence. While it is acknowledged that the specification does provide examples of species which have modifications of the amino acid sequence from the wild type parent the few species disclosed are clearly not representative of the genus claimed. Contrary to applicants statement the effects of substitutions within a reporter protein is **not** predictable, and the specification fails to provide any structure to function correlation such that one could predict the effect of **any** amino acid substitution at **any** position in **any** reporter protein. As such the few disclosed species can not be considered to be representative of the enormous and diverse genus claimed and the scope of the claims is not commensurate with the enablement provided in the specification.

The rejection of Claims 1-9, 11, 12, 14, 15, 20, 21, 24-39, 41-45, 60-63 and 67-68 under 35 U.S.C. 103(a) as being unpatentable over the Sherf et al. (US Patent 5,670,356) in view of Zolotukhin et al. (US Patent 5,874,304) and Iannacone et al. is maintained.

Applicants again argue against the rejection by piecemeal pointing out the deficiencies of each reference individually. However, this is not convincing as it is what the combination of

Art Unit: 1652

references suggests that is cited. Although each reference discloses a different way to modify the coding sequence of a gene to increase expression, the skilled artisan clearly would be motivated to combine these different methods in order to achieve the benefits of all. One would clearly expect the combination to be better than each of the methods individually.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (571) 272-0937. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.



---

Rebecca Prouty  
Primary Examiner  
Art Unit 1652